



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94298d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3003383395

September 15, 2003

Jerry C. Atkin
President and CEO
SkyWest Airlines, Inc.
444 South River Road
St. George, Utah 84790

WARNING LETTER

Dear Mr. Atkin:

On July 15, 2003, FDA conducted an inspection of your facility located at 200 Fred Kane Drive, Suite 100, Monterey, California, which provides aircraft watering point and lavatory waste service to various airlines at Monterey Peninsula Airport. The observations made during the inspection revealed that your facility is in violation of Section 361 of the Public Health Service Act and the Interstate Conveyance Sanitation regulations at Title 21, Code of Federal Regulations, Part 1250 (21 CFR 1250). FDA's observations were listed on Form FDA 483, Inspectional Observations, which was issued to and discussed with Timothy R. Laizure, Station Manager. Form FDA 2528, Inspection Summary - Airline Service Area or Watering Point Sanitation, was also provided to Mr. Laizure. Copies of both documents are enclosed for your ready reference.

During the inspection, the following observations were noted:

The dual connection unit which is attached to the potable water system has no backflow device to prevent contamination (21 CFR § 1250.67). Specifically, the dual connection unit is a "Y" shaped hose connector attached to the faucet. One of the outlets to the dual connection unit is used to fill the lavatory waste cart, and the other outlet is used for the potable water cart, which is not marked or labeled.

The above items are not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with all applicable statutes and regulations enforced by FDA.

Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use for a period of thirty (30) days. A "Provisional" classification

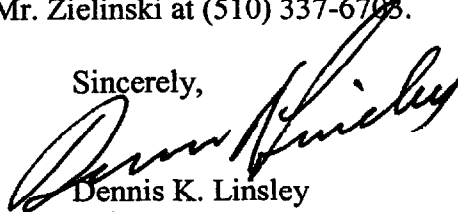
means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made by the time of the next inspection, this facility will be reclassified as "Not Approved" for carrier use. Assignment of "Not Approved" status for food service facilities means that food and beverages from this facility may not be used by interstate conveyances until the violations have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps that you have taken to prevent a recurrence of the cited deficiencies. Your response should include a discussion of any delays you foresee in achieving correction and a deadline by which correction can be expected. Your response should be directed to:

Randall P. Zielinski
Interstate Travel Specialist
Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

You may wish to fax your response to Mr. Zielinski at (510) 337-6708.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosures:

- Form FDA 483
- Form FDA 2528